K072354
1 of 3

510(k) Summary

Date Prepared: August 20, 2007

Submitted by:
Accellent, Inc.
100 Fordham Rd.
Wilmington, MA 01887
Establishment Registration: To be submitted to FDA upon 510(k) clearance.

Official Correspondent:
Karl Steineck
Quality Manager
Accellent, Inc.

DEC 07 2007

Telephone Number: 303-432-4939
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Manufacturing Facility:
Accellent Inc.
S.A. De C.V.
1525 Hertz Street
Industrial Park J. Bermudez of C.D.
Juarez, Chihuahua 32470
Mexico CP
Establishment Registration: 9680001

Submitted Device
Trade Name: Disposable Guidewire
Model Numbers:
G-V220-3527S, G-V220-3527A,
G-V220-3545S, G-V220-3545A,
G-V220-2527S, G-V220-2527A,
G-V220-2545S, G-V220-2545A,
G-V230-3527S, G-V230-3527A,
G-V230-3545S, G-V230-3545A.

Common Name: Guidewire
Classification: Endoscope and accessories 21 CFR 876.1500

Identification. An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the user's eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of

K072354
2 of 3

device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binolcular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

Predicate Device: Olympus Guidewire G-205-3545S, G205-3545A #K021179

Product Description:
Coated guidewire. Removal of the guidewire is not necessary during sphinctecterotomy. Three guidewire configurations, straight, V taper and angled tip. These instruments have been designed to be used with the Olympus Endo-Therapy Accessories.

Intended Use of the Device(s):
This instrument has been designed to be used with the Olympus endo-therapy Accessories. The instrument is used for the guiding and exchanging endoscopic accessories for the biliary duct, including but not limited to the common bile, cystic, pancreatic and right and left hepatic ducts.

Statement of substantial equivalence:
When compared to the predicate device, the new device does not incorporate any significant changes in the intended use, method of operation, materials, or design that could affect the safety or effectiveness.

Table 1
Comparison between the predicate device and new device

Feature	Olympus Guidewire (Predicate Device)	Olympus ERCP Guidewire
Intended use	This instrument has been designed to be used with the Olympus Endo-therapy Accessories. The instrument is used as a guidewire of endoscopic accessories for biliary duct, including but not	This instrument has been designed to be used with the Olympus Endo-therapy Accessories. The instrument is used as a guidewire of endoscopic accessories for biliary duct, including but not limited to the common bile, cystic, pancreatic, right and left

	limited to the common bile, cystic, pancreatic, right and left hepatic ducts.	hepatic ducts.
Materials	Nickel Titanium alloy	Nickel Titanium alloy
	Polyurethane –coating	Polytetrafluoroethylene PTFE
	Hydrophilic –coating	Pebax
	Silicone - coating	Lubricious
Sterilization Method	Ethylene Oxide	Ethylene Oxide

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 07 2007

Mr. Karl Steineck
Quality Manager
Accellent, Inc.
5000 Independence Street
ARVADA CA 80002

Re: K072354
Trade/Device Name: Disposable Guidewire
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: November 9, 2007
Received: November 13, 2007

Dear Mr. Steineck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K072354
1 of 1

Indications for Use

510(k) Number (if known): _____

Device Name: Disposable Guidewire

Indications for Use:

This instrument has been designed to be used with the Olympus endo-therapy Accessories. The instrument is used for the guiding and exchanging endoscopic accessories for the biliary duct, including but not limited to the common bile, cystic, pancreatic and right and left hepatic ducts.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072354

(Posted November 13, 2003)